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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,162	BROWN ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election with traverse of Group II in the reply filed on February 28, 2007 is acknowledged. First, it is noted that with respect to the second part of the restriction requirement set forth in the Office action mailed January 9, 2007, namely the restriction between Sequence ID No. 1 and No. 2, Examiner hereby withdraw only this part of the restriction requirement and examination of both sequences are made in the present Office action. As to the first part of the restriction requirement, i.e., the restriction between the method and the product claims, Applicants' arguments are not found persuasive. The traversal is on the ground(s) that the members of the groups are sufficiently few in number that a search and examination of the groups can be made without creating a serious burden on Examiner and there would be no serious burden because the search terms would probably be overlapping. This is not persuasive because the search for the polypeptide tag does not require a search of the method steps, such as attaching the polypeptide tag to a protein and binding the polypeptide tag to a solid surface. (It is noted that the method claims will be rejoined if claims to nonelected process of making or using depend from or otherwise require all limitations of an allowable product claim.) Applicants also argue that the instant international application complies with PCT rules of unity of invention requirements and thus should not be subject to restriction requirement. However, this is not persuasive because Applicants do not distinctly and specifically point out the supposed errors in the

restriction requirement of January 9, 2007, which set forth the reasons why there is a lack of unity of invention in the present application.

Claims 1-20 and 27-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 28, 2007.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21, 24-26, 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "The cell" in line 1. There is insufficient antecedent basis for this limitation in the claim.

As to claims 21, 24-26 and 33-36, there is no indication of whether the claimed subject matter is open or closed (that is, there is no transitional phrases such as "comprising" or "consisting of".)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al., 5,486,452.

As to claim 21, Applicants claim a polypeptide tag that is capable of controlling the orientation of proteins immobilized on a microporous material, wherein said microporous material is zeolite or similar solid surfaces. (It is noted that neither the microporous material nor zeolite nor protein is not positively recited as part of the claimed invention, which is directed to a polypeptide tag. The claim only recites that the tag is *capable* of controlling orientation of proteins that are immobilized on a microporous material, in particular, zeolite.) It is noted that Applicants' define in the specification the term "similar solid surfaces" as relating to solid surfaces selected from the group consisting of intercalated hydrotalcites and intercalated clays, and other aluminum silicates, aluminum phosphates, clays, metal oxides hydrotalcites, oxide powders, activated carbon, mica, glass and quartz (see page 10, lines 21-24; see also

claims 15 and 34 for some specifics), and thus the term "similar solid surfaces" is limited to the definition given by Applicants.

Gordon et al. teach antigens or immunoglobulins adhered to the porous surface of a solid support and are suitable for reaction with antibodies or antigens in biological liquids and for their detection by any of the known immunological assay methods, such as detection with use of an indicator antibody, e.g., radioactively labeled (indicator) antibody or an (indicator) antibody coupled with an enzyme giving a color reaction, wherein the term indicator means a molecule which has a group attached to it which generates a detectable and measurable signal under specified conditions (col. 2, line 59 – col. 3, line 11.) The porous support may be any material with sufficient surface porosity to allow access by immunoglobulins and a suitable surface affinity to bind antigens, for example, zeolite (col. 5, lines 3-8, and 30-36.) The porous zeolite disclosed by Gordon et al. is deemed to be the claimed microporous zeolite because it is porous and is small enough that it allows access by immunoglobulins. While Applicants state in the specification that *useful* meso- and microporous materials have a pore size in the range of 1-500 ANG, Applicants do not define "microporous" to refer to a particular pore size and thus the porous zeolite disclosed by Gordon et al. is considered to be microporous, i.e., in the micro-scale, since it allows access to molecules such as immunoglobulins. The label such as the enzyme is deemed to be the polypeptide tag that is capable of controlling the orientation of proteins immobilized on a microporous material. Applicants do not recite *how* the polypeptide tag controls the orientation of immobilized proteins and thus the enzyme bound to a protein that is in

turn bound to or immobilized on a microporous material (i.e., zeolite) is considered to be controlling the orientation of the immobilized protein because it adds bulk to the complex and any change in the orientation or movement of the protein is considered to be controlling the orientation of the protein.

As to claim 24, the enzyme is deemed to be the polypeptide tag provided on a subunit of a protein (i.e., antibody, col. 3, lines 7-8).

Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by Feder et al., 2003/0064438, in light of Gordon et al., 5,486,452.

As to claim 32, Applicants claim a cell comprising a surface molecule comprising the polypeptide tag according to claim 21, and claim 21 recites a polypeptide tag that is capable of controlling the orientation of proteins immobilized on a microporous material, wherein said microporous material is zeolite. (It is noted that neither the microporous material nor zeolite nor protein is not positively recited as part of the claimed invention of claim 32, which is directed to a cell having a polypeptide tag. Moreover, claim 21 only recites that the tag is *capable* of controlling orientation of proteins that are immobilized on a microporous material, in particular, zeolite.)

Feder et al. teach fusion peptides that can include Myc-tag, hemagglutinin-tag, histidine-tag, FLAG-tag, etc, or fusions to any amino acid sequence that allows the fusion polypeptide to be anchored to a cell membrane, allowing the polypeptide of

interest (in particular the HGPRBMY2 domain) to be exhibited on the cell surface (paragraph 0211). Feder et al. also teach that the polypeptides can be conjugated or fused to a compound, such as an enzyme, fluorescent polypeptide, or luminescent polypeptide which provide a marker function (paragraph 0212). Feder et al. moreover teach that host cells themselves may be used in situations where it is important not only to retain the structural and functional characteristics of the polypeptide of interest, but to assess biological activity, e.g., in drug screening assays (paragraph 0225.) The cell conjugated to a polypeptide tag is considered to be Applicants' claimed cell comprising a surface molecule comprising the polypeptide tag.

Applicants do not recite *how* the polypeptide tag controls the orientation of immobilized proteins and thus a polypeptide tag that is capable of binding to a protein that is bound to or immobilized on a microporous material (i.e., zeolite) is considered to be controlling the orientation of the immobilized protein because it adds bulk to the complex and any change in the orientation or movement of the protein is considered to be controlling the orientation of the protein. A molecule, e.g., protein, is capable of adhering to a zeolite, as evidenced by Gordon et al. (col. 2, lines 65-66), and thus the Feder et al. polypeptide tag, which is capable of binding to a molecule that is capable of adhering to a zeolite, is deemed to be capable of controlling the orientation of the immobilized protein because it adds bulk to the complex and any change in the orientation or movement of the protein is considered to be controlling the orientation of the protein. (It is noted that Applicants do not specify where in or on the zeolite the polypeptide tag or cell is located.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al., 5,486,452, in view of Wagner et al., 6,329,209.

Gordon et al. disclose the invention substantially as claimed (see above) except for the polypeptide tag comprising at least two lysine residues (claim 22) or at most 21-500 amino acid residues (claim 23).

Wagner et al. teach that an affinity tag can be readily introduced into recombinant proteins to facilitate oriented immobilization by covalent binding to a solid support. The affinity tag may optionally comprise a poly(amino acid) tag that comprises from about 2 to about 100 residues of a single amino acid, optionally interrupted by residues of other amino acids. The amino acid tags are preferably composed of two to twenty residues of for example lysines (col. 21, lines 41-60.) Wagner teach that the position of the amino acid tag can be at an amino-or carboxy-terminus of the protein-capture agent which is a protein, or anywhere in between, as long as the protein-binding region of the protein-

capture agent, such as the antigen-binding region of an immobilized antibody moiety, remains in a position accessible for protein binding (col. 21, line 63 - col. 22, line 1.)

While the zeolite solid support disclosed by Gordon et al. is different from the organic thinfilm disclosed by Wagner et al. (col. 21, line 45) as the solid support, Gordon et al. however teach that the disclosed invention is suitable for assay detection by any of the known immunological assay methods (col. 3, lines 1-3) and disclose use of radioactively labeled antibody or an antibody coupled with an enzyme giving a color reaction as examples (col. 3, lines 4-8). Thus Gordon et al. teach use of the zeolite as a solid support with detectable labels in general and does not limit the labels or detection method to any particular type but rather suggest that other known labels and methods of detection known in the art may be used. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize amino acid tags disclosed by Wagner et al. as the specific type of labels generally disclosed by Gordon et al. for use on a zeolite solid support because Gordon et al. suggest that various known labels and detection methods may be used and Wagner et al. moreover teach that amino acid tags are readily incorporated into proteins to be immobilized while allowing for the protein to remain in a position accessible for protein binding. That is, the skilled artisan would have been motivated to utilize the amino acid tags disclosed by Wagner et al. on the Gordon et al. zeolite solid support because of the ease of use of such tags as they are readily incorporated into proteins without affecting the protein's ability to bind in the assay, as taught by Wagner et al.

As to claim 23, as noted above, Wagner et al. teach that the affinity tag may optionally comprise a poly(amino acid) tag that comprises from about 2 to about 100 residues of a single amino acid, optionally interrupted by residues of other amino acids (col. 21, lines 41-60.)

Allowable Subject Matter

Claims 25, 26 and 33-35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/29/07

ANN YEN LAM
PATENT EXAMINER